

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) An apparatus comprising:
an electrical lead comprising a lead body and an electrical conductor; and
an electrode coupled to the electrical conductor, wherein the electrode includes a coating disposed on at least a portion of a surface of the electrode, the coating including three or more layers, with a first layer comprising an insulative polymeric base material adjacent to and in contact with at least a portion of the surface of the electrode for insulating at least a portion of the electrode and increasing an impedance of the electrode ~~including an insulative polymeric base material~~, a second layer disposed over and in contact with at least a portion of the first layer, the second layer including an insulative polymer matrix material and a first pharmacological agent, and a third layer disposed over the second layer, wherein the third layer consists of a ~~second pharmacological agent~~ drug.
2. (Original) The apparatus of claim 1, wherein the electrode includes a helical tip.
3. (Previously Presented) The apparatus of claim 1, wherein the first pharmacological agent comprises an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an antiproliferative agent, or a combination thereof.
4. (Original) The apparatus of claim 3, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
5. (Cancelled)

6. (Currently Amended) The apparatus of claim 1, wherein ~~second pharmacological agent comprises the drug~~ is any one of an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent ~~[[,]] or an antiproliferative agent, or a combination thereof.~~

7. (Original) The apparatus of claim 6, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.

8. (Previously Presented) The apparatus of claim 1, wherein the polymeric base coat is ethylene vinyl alcohol.

9. (Previously Presented) The apparatus of claim 1, further comprising a fourth layer disposed over and in contact with the second layer, wherein the fourth layer includes a porous polymeric barrier having a porosity sufficient to regulate a release of the first pharmacological agent from the second layer.

10-15. (Cancelled)

16. (Currently Amended) A system comprising:

an electrical pulse generator;

an electrical lead releasably coupled to electrical pulse generator, wherein the electrical lead includes a lead body and an electrical conductor; and

an electrode coupled to the electrical conductor, wherein an outer surface of the electrode comprises a coating disposed on at least a portion of an outer surface of the electrode such that the outer surface of the electrode comprises a coated region and an uncoated region, the coating including three or more discrete layers comprising a first layer including an insulative polymeric base material adjacent to and in contact with the outer surface of the electrode such that an impedance of the electrode is increased, a second layer disposed over and in contact with the first layer, the second layer including an insulative polymer matrix material and a first pharmacological agent, and a third layer disposed over the second layer, wherein the third layer consists of a ~~second pharmacological agent~~ drug.

17. (Original) The system of claim 16, wherein the electrode includes a helical tip.
18. (Previously Presented) The system of claim 16, wherein the first pharmacological agent comprises an antiarrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent, an antiproliferative agent, or a combination thereof.
19. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
20. (Original) The system of claim 18, wherein the anti-inflammatory agent is dexamethasone.
21. (Cancelled)
22. (Currently Amended) The system of claim ~~16~~ 21, wherein the ~~second pharmacological agent comprises~~ drug is any one of an anti-arrhythmic agent, an angiogenic growth factor, an anti-inflammatory agent~~[[,]]~~ or an anti-proliferative agent~~, or a combination thereof~~.
23. (Original) The system of claim 22, wherein the anti-inflammatory agent is dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.
24. (Previously Presented) The system of claim 16, wherein the polymeric base coat is ethylene vinyl alcohol.
25. (Previously Presented) The system of claim 21, further comprising a fourth layer disposed between the second layer and the third layer in contact with the second layer, wherein the fourth layer comprises a porous polymeric barrier having a porosity sufficient to regulate a release of the first pharmacological agent from the second layer.
- 26-29. (Cancelled)

30. (Currently Amended) An apparatus comprising:
an electrical lead comprising a lead body and an electrical conductor; and
an electrode coupled to the electrical conductor, wherein the electrode includes a coating ~~disposed on-at least~~ a portion of a surface of the electrode, the coating including three or more layers, with an inner layer including a first pharmacological agent ~~in~~ dispersed within a insulative polymer matrix for regulated, chronic release of the first pharmacological agent, ~~and~~ an outer layer consisting of a ~~second pharmaceutical agent drug~~ such that the ~~second pharmaceutical agent drug~~ of the outer layer is exposed to tissue upon implant of the electrode, and a middle layer disposed between the inner layer and the outer layer, wherein the middle layer includes a porous polymer barrier and is adjacent to and in contact with the inner layer and not adjacent to the surface of the electrode.

31. (Original) The apparatus of claim 30, wherein the electrode includes a helix.

32. (Previously Presented) The apparatus of claim 30, further including a fourth layer directly adjacent a surface of the electrode comprising a polymer primer layer, with the inner layer adjacent the polymer primer layer.

33. (Previously Presented) The apparatus of claim 30, wherein the first pharmaceutical agent in the polymer matrix includes an anti-inflammatory drug.

34. (Previously Presented) The apparatus of claim 30, wherein the first pharmacological agent in the polymer matrix includes an anti-proliferative drug.

35. (Currently Amended) A method comprising:
coating ~~at least~~ a portion of a surface of an electrode with a first layer, wherein the first layer comprises an insulative polymeric base coat for insulating a portion of the electrode and increasing impedance of the electrode;
coating the first layer of the electrode with a second layer, wherein the second layer comprises an insulative polymer and at least ~~one~~ a first pharmacological agent, and at least partially coats the first layer and not the surface of the electrode; and

coating the second layer with a third layer, wherein the third layer consists of ~~at least one~~
a drug~~pharmacological agent~~.

36. (Currently Amended) The method of claim 35, wherein the ~~pharmacological agent~~
~~comprises~~ drug is any one of an anti-arrhythmic agent, an angiogenic growth factor, an anti-
inflammatory agent~~[[,]]~~ ~~or an antiproliferative agent, or a combination thereof.~~

37. (Original) The method of claim 36, wherein the anti-inflammatory agent is
dexamethasone, clobetasol, beclomethasone, or a pharmaceutically acceptable salt thereof.

38. (Original) The method of claim 35, wherein the polymeric base coat is ethylene vinyl
alcohol.

39. (Currently Amended) The method of claim 35, further comprising a fourth layer
positioned between the second and third layer, wherein the fourth layer comprises a porous
polymeric barrier.

40. (Currently Amended) The method of claim 39, wherein the second layer comprises a
matrix including a polymer and at least one pharmacological agent and ~~the third~~ fourth layer
regulates the release of the pharmacological agent from the matrix.

41- 43. (Cancelled)

44. (Currently Amended) The method of claim 35, further comprising the step of contacting
an exterior surface of the electrode with a composition ~~wherein the coating is applied by~~
~~contacting an exterior surface of the electrode with a composition~~ comprising the ~~at least one~~
insulative polymer and the first ~~at least one~~ pharmacological agent to form the second layer.

45. (Original) The method of claim 44, wherein the contacting includes spraying.

46. (Previously Presented) The apparatus of claim 1, wherein the first layer is between 1 and 100 microns thick.

47. (Previously Presented) The apparatus of claim 46, wherein the amount of the at least one pharmacological agent present in the second layer is up to 60% by weight of the second layer.

48. (Previously Presented) The system of claim 16, wherein the first layer is between 1 and 100 microns thick.

49. (Currently Amended) The system of claim 48, wherein the amount of the ~~at least one~~ first pharmacological agent present in the second layer is up to 60% by weight of the second layer.

50. (Currently Amended) The apparatus of claim 30, wherein the amount of the ~~at least one~~ first pharmacological agent present in the inner layer is up to 60% by weight of the inner layer.

51. (Previously Presented) The method of claim 35, wherein the first layer is between 1 and 100 microns thick.

52. (Currently Amended) The method of claim 51, wherein the amount of the ~~at least one~~ first pharmacological agent present in the second layer is up to 60% by weight of the second layer.

53. (New) The apparatus according to claim 1, wherein the insulative polymeric base material is selected from the group consisting of Parylene, polyurethanes, polyacrylates, polymethacrylates, polyamides, polyethers, polysiloxanes, and polyepoxy resins.